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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,372	03/01/2002	Richard N. Ellson	7610-0042.21	4669

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REED & EBERLE LLP
800 MENLO AVENUE, SUITE 210
MENLO PARK, CA 94025

EXAMINER	
BERMAN, JACK I	

ART UNIT	PAPER NUMBER
2881	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,372	ELLSON ET AL.	
	Examiner	Art Unit	
	Jack I. Berman	2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s) _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-17, 19-21, 26, 32-38, 40-45, 47, 48, 51-53, and 59-63 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams et al. Williams et al. discloses a method of preparing a plurality of molecules for analysis comprising preparing an array of fluid reservoirs on a substrate by depositing droplets of analysis-enhancing source fluid from the reservoirs onto a sample substrate by applying focused acoustic energy to each of the plurality of fluid reservoirs to cause the ejection of droplets that may then be directed to the sample substrate. In paragraph [0069], Williams et al. teaches:

> "In one embodiment, the methods of the present invention may be used to pair certain ligands (i.e., a molecular group that binds to another entity to form a larger more complex entity) and binding partners for such ligands. For example, certain biological molecules are known to interact and bind to other molecules in a very specific manner. Essentially any molecules having a high binding specificity or affinity for each other can be considered a ligand/binding partner pair, e.g., a vitamin binding to a protein, a hormone binding to a *cell-surface [emphasis supplied]* receptor, a drug binding to a *cell-surface [emphasis supplied]* receptor, a glycoprotein serving to identify a *particular cell [emphasis supplied]* to its neighbors, an antibody (e.g., IgG-class) binding to an antigenic

> determinant, an oligonucleotide sequence binding to its complementary fragment of RNA or DNA, and the like."

It is thus clear that Williams et al. is concerned with contacting cell surfaces with various materials. What is not clear is whether the cells of interest are in the source fluid or on the target to which the droplets of source fluid are directed. It would seem that, since the surfaces of the cells are of interest, the method would involve directing the droplets of material onto these surfaces, but this is not unambiguously stated in the published application. However, paragraph [0070] of the application goes on to teach:

> Such pairings are useful in screening techniques, synthesis techniques, and the like. Accordingly, in one embodiment of the present invention, screening assays may be performed in which the binding specificity of one compound for another is sought to be determined. For example, multiple test compounds (i.e., putative ligands, optionally having detectable labels attached) may be screened for specific interaction with a selected binding partner. Such assays may be carried out by positioning one of a plurality of putative ligands in each pool of an array of source fluids. The target may comprise, for example, an array of target zones, each zone having affixed to it a sample of the binding partner for which specific binding is sought to be identified. Employing the methods of the invention, a droplet of each putative ligand can be ejected to a target zone and the target thereafter washed under defined conditions. Afterwards, each of the target zones is inspected to determine whether binding of the putative ligand has occurred. Binding of a putative ligand serves to identify that compound as a ligand for the binding partner. Binding can easily be identified by any method known to those of skill in the art. By employing detectable labeled test compounds, binding can readily be determined by identifying a labeled compound bound to the target. *Of course, such assays may be reversed, i.e., the selected binding partner may be used as a labeled source compound, while putative ligands are arrayed onto the target. [Emphasis supplied]*

This means that since the published application teaches to use the method for depositing droplets as a means for studying the interaction of cell surfaces with selected molecules and the only ways to do this are by including the cell as a target or in the source fluid, and the source and target are interchangeable, then even if Williams et al. does not inherently use a cell as the target,

instead using it in the source material with a possible ligand as the target material, it would have been obvious to a person having ordinary skill in the art to do so and use the possible ligand as the source material because these are the only two possible arrangements in the Williams et al. method and Williams et al. teaches that the two arrangements are equivalent. In paragraph [0076], Williams et al. teaches that the source fluid can comprise fluorescent, magnetic, or nuclear (i.e. radioactive) labels. In paragraphs [0059-0062], Williams et al. teaches that the source fluid may be a biomolecule, which may be either nucleotidic or peptidic or even cells. In paragraph [0057], Williams et al. teaches:

> "Because these methods may be employed in high throughput applications, it is preferred that methods of the invention further comprise user-defined positioning of the acoustic liquid deposition emitter relative to an array of source wells, thus providing for user-defined association of the acoustic liquid deposition emitter with a selected pool of source fluid for ejection of a droplet therefrom. This can be accomplished by a variety of methods. For example, in the case where a multi-well plate is employed as the source fluid containment structure, a computer-controlled translator (e.g., an actuator, or the like) can manipulate the position of the multi-well plate or a movable stage upon which the multiwell plate rests. Thus, a selected well or a selected succession of wells is placed over the acoustic deposition emitter, as the source fluid contained in each well is needed for the application being conducted (e.g., oligonucleotide synthesis, or the like). In a related embodiment, the acoustic deposition emitter may be moved rather than the source plate. For example, the source fluid containment structure may remain fixed in position and the acoustic liquid deposition emitter may be moved relative to a well or particular source fluid of interest contained in or on the source fluid containment structure."

In paragraph [0058], Williams et al. further teaches:

> "The target may comprise an array of target zones or target spots to which source fluid is directed. As described above, with respect to the source fluid and acoustic deposition emitter, the target may also be moveable relative to a source fluid. For example, the target may be moved relative to a source fluid to be ejected thereby allowing for selected receipt at the target of a desired ejected source fluid droplet. The target may be positioned so that each target zone can be selectively positioned over the selected pool of source fluid. A computer

> controlled actuator arm, or the like can accomplish positioning of the target. It is presently preferred that both the target and the source fluid containment structure be positionable via separate computer-controlled actuators. Thus, the non-contact fluid transfer/deposition technology described herein provides for precise targeting of individual source fluids to selected target zones."

In paragraph [0076], Williams et al. further teaches:

> "Following contacting of the "unknown" polynucleotide with the target array of oligonucleotides, the target array is washed at the appropriate stringency and the presence and location of hybridized-labeled polynucleotide is determined using scanning analyzers or the like."

Claims 2-5, 18, 22, 39, 46, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. As is discussed above, the Williams et al. method is described as being useful for the analysis of cellular samples. The published application does not define the source for the sample cells, but it is well known in the art to collect cells for analysis from either cultures or tissues, including mammalian tissues. It would have been obvious to a person having ordinary skill in the art to collect cells for analysis by the Williams et al. method from such known sources. It would also have been obvious to extract biomolecules of the type used in the Williams et al. method from cells because that is the most common source for these types of biomolecules (such as nucleotides). While Williams et al. teaches in paragraph [0076] to wash a target sample after the deposition of the source fluid and before analysis takes place, it would have been obvious to a person having ordinary skill in the art to allow volatile components in the source fluid to evaporate instead of applying a different fluid to the target to wash away unwanted components. The technique used to remove the unwanted components from the source fluid deposited on the cellular sample would depend on the nature of the source fluid, which is (since the Williams et al. method is disclosed as a research method) inherently a matter for routine experimentation. Since Williams et al. also teaches in paragraph [0076] to analyze each

of an array of designated sites on a target, it would have been obvious to a person having ordinary skill in the art to map the target, i.e. to record the analysis results for each site along with a record of the arrangement of the sites because it would make no sense to analyze each of an array of sites where the sites are known to be different from each other and not record which analysis result came from which site. Williams et al. teaches to use "scanning analyzers or the like" to analyze the target after the source fluid has been deposited on it, but doesn't specify a particular type of analyzer. The use of optical detectors, radiation detectors, and magnetic detectors to detect fluorescent, radioactive, and magnetic labels, respectively, is well known in the art and it would have been obvious to a person having ordinary skill in the art to use one of these detectors as the unspecified analyzer in the Williams et al. system.

Claims 27-31, 54, 56-58, and 64-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. as applied to claims 2-5, 18, 22, 39, 46, and 55 above, and further in view of Caprioli. As is discussed above, Williams et al. teaches to use "scanning analyzers or the like" to analyze the target after the source fluid has been deposited on it, but doesn't specify a particular type of analyzer. Caprioli teaches to analyze the composition of a cellular sample by scanning the sample with a laser to release and ionize molecules from the sample surface for analysis in a mass spectrometer. It would have been obvious to a person having ordinary skill in the art to use the mass spectrometer analysis system disclosed in Caprioli as the unspecified analyzer in the Williams et al. system.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-25, 26-28, 29-31, 33-35, 49, and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 145-150, 156, 157-159, 151-153, 149, and 150, respectively, of copending Application No. 10/066,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to a person having ordinary skill in the art to use the "method for preparing a sample surface for analysis" claimed in 10/066,546 to prepare the surface of a cell sample for analysis since the surface of a cell sample does constitute a surface and the method claimed in 10/066,546 appears to cover the preparation of any kind of surface. It would also have been obvious to a person having ordinary skill in the art, with respect to claims 49 and 50, to provide the apparatus required to practice the method claimed in claims 149 and 150 of 10/066,546.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack I. Berman whose telephone number is (703) 308-4849. The examiner can normally be reached on M-F (8:30-6:00) with every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on (703) 308-4116. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

Jack I. Berman
Primary Examiner
Art Unit 2881

jb
May 28, 2003